DEC 1 8 2006

titioner's Docket No. MPI00-212CP1CN1M

PATENT

| IN | THE | UNITED | STATES | PATENT A | ND TRADEMAI | RK OFFICE |
|----|-----|--------|--------|----------|-------------|-----------|
| | | | | | | |

| In re application of: | Anthony J. Coyle, et al. | | |
|-----------------------|---|------------|---------------------------|
| Application No.: | 10/644,671 | Group No.: | 1644 |
| Filed: | August 20, 2003 | Examiner: | OUSPENSKI, ILIA I. |
| For: | SCREENING METHOD B7 FAMILY (as amended | | MOLECULES, MEMBERS OF THE |

Mail Stop Amendment

Confirmation No. 6437

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 **TRANSMITTAL** 1. Transmitted herewith for this application is/are: This Transmittal (3 pages - in duplicate); Amendment and Response (13 pages); b. Copy of Statement of Biological Culture Deposit (2 pages): c. d. Copy of ATCC Receipt Form (1 page); e. Copy of ATCC Deposit Forms (4 pages); f. Exhibit A (1 page); Copy of Information Disclosure Statement as filed on August 20, 2003 (2 pages); g. Copy of Form PTO/SB/08A and Form PTO/SB/08B as filed on h. August 20, 2003 (3 pages); i. Copy of References cited in Information Disclosure Statement (Citation Nos. B1-B12, C1, C3-C4, C6-C12, and C14); Power of Attorney and Correspondence Address Indication Form (1 page); j. Statement under 37 CFR 3.73(b) (1 page); k. 1. Copy of Notice of Recordation, Recordation Form Cover Sheet, and executed Assignment (15 pages); and Return postcard m. **STATUS** Applicant is other than a small entity. CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10* I hereby certify that, on the date shown below, this correspondence is being: **MAILING** deposited with the United States Postal Service in an envelope addressed to Mail Stop Amendment, Commissioner for × Patents, P.O. Box 1450, Alexandria, VA 22313-1450. 37 C.F.R. SECTION 1.8(a) 37 C.F.R. SECTION 1.10* X with sufficient postage as first class mail. as "Express Mail Post Office to Addressee"

Mailing Label No. **TRANSMISSION** transmitted by facsimile to the Patent and Trademark Office (571-273-8300) Signature Date: December 14, 2006 Sean Hunziker/Beverly Sotiropoulos (type or print name of person certifying)

*WARNING: Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b). "Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(Page 1 of 3)

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Practitioner's Docket No. MPI00-212CP1CN1M

PETITION FOR EXTENSION OF TIME

3. The proceedings herein are for a patent application and the provisions of 37 C.F.R. 1.136 apply. Applicant petitions for an extension of time under 37 C.F.R. 1.136 (fees: 37 C.F.R. 1.17(a)(1)-(3)) for a three month extension:

Fee:

\$1,020.00

Extension fee due with this request

\$1,020.00

\$0.00

If an additional extension of time is required, please consider this a petition therefor.

FEE FOR CLAIMS

4. The fee for claims (37 C.F.R. 1.16(b)-(d)) has been calculated as shown below:

| (Col. 1) | | (Col. 2) | | (Col. 3) | OTHER THAN A SMALL ENTITY | | | |
|---------------------------------|--|----------|---------------------------------------|----------|---------------------------|---------------------|----|------------|
| | Claims Remaining After Amendment | r | Highest No. Previously Paid For | | Present Extra | Rate | | Addit. Fee |
| Total | 10 | Minus | 23 | = | 0 | \$50.00 | = | \$0.00 |
| Indep. | 1 | Minus | 2 | = | 0 | \$200.00 | = | \$0.00 |
| Multiple Dependent Claims | no | | no | | | \$360.00 | = | \$0.00 |
| | | | | - | | Total Addit. Fee | _, | \$0.00 |

Total additional fee for claims required

FEE PAYMENT

5. Charge Account No. 501668 the sum of \$1,020.00 (which includes the extension fee). A duplicate of this transmittal is attached.

Practitioner's Docket No. MPI00-212CP1CN1M

FEE DEFICIENCY

- 6. If any additional extension and/or fee is required, charge Account No. 501668. If any additional fee for claims is required, charge Account No. 501668.
- 7. Correspondence Address
 Direct all future correspondence to:

Customer Number 30405 OR

Intellectual Property Department
MILLENNIUM PHARMACEUTICALS, INC.
40 Landsdowne Street
Cambridge, MA 02139

December 14, 2006

MILLENNIUM PHARMACEUTICALS, INC.

Ву

Jonathan K. Hamm, Ph.D. Registration No. 59,608 40 Landsdowne Street Cambridge, MA 02139 Telephone – (617) 679-7166



Application No.:

In re application of: Colye, Anthony, et al.

09/620,461



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group No.:

1644

| Filed | l: July 20, 2000 | Examiner: Roark J. |
|---------|---|--|
| For: | B7-H2 MOLECULES, M THEREOF | EMBERS OF THE B7 FAMILY AND USES |
| | nmissioner for Patents hington, D.C. 20231 | |
| | STATEMENT OF BIO | OGICAL CULTURE DEPOSIT |
| I | Name of Applicant or Assignee's representative | hereby state: |
| 1. depo | That the following culture(s) referred to sited: | in the specification of this application have been |
| pfrho | ob165c3L | PTA-2084 |
| pfrho | ob35911S | PTA-2085 |
| | Strain | Accession number |
| | That the date of the above deposit is before the | s: |
| | American Type Culture Collection (ATC | e of depository |
| | | |
| | 10801 University Blvd Manassas, VA 20 | ess of depository |
| and y | That a statement that the cultures deposited | with the above named depository was (were) viable on the date of deposit is attached. Such statement is |
| I here | by certify that, on the date shown below, this correspo | 37 C.F.R. SECTIONS 1.8(a) and 1.10* ondence is being: MAILING |
| X | | an envelope addressed to the Assistant Commissioner for 37 C.F.R. SECTION 1.10* |
| X | with sufficient postage as first class mail. | as "Express Mail Post Office to Address" Mailing Label No. |
| 0 | TRA transmitted by facsimile to the Patent and Tradem | ANSMISSION Jark Office. Jentile |
| Date: | 23 September 2002 (Monday) | Signature Diana Gentile |
| *WAR | RNING:Each paper or fee filed by "Express Mail" mu | (type or print name of person certifying) ist have the number of the "Express Mail" mailing label placed |

thereon prior to mailing. 37 C.F.R. section 1.10(b). "Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

- 5. That, with respect to the permanence of the culture(s) deposit:
 - a. the depository is an official depository, in accordance with the Budapest Treaty for the above deposited cultures;
 - b. the depository affords permanence of the deposit for at least 30 years or at least 5 years after the most recent storage request, whichever is longest; and
 - c. evidence that permanent availability of the microorganism is assured is provided in the form of the attached copy of the contract with the above-mentioned depository with respect to the deposited cultures.

I affirm that should the microorganisms mutate, become nonviable or be inadvertently destroyed, applicants will replace such microorganisms for at least 30 years from the date of the original deposit, or at least 5 years from the date of the most recent request for release of a sample or for the life of any patent issued on the above-mentioned application, whichever period is longer.

- 6. That, with respect to availability of the cultures, I affirm that the deposit has been made under conditions of assurance of:
 - a. ready accessibility thereto by the public if a patent is granted whereby all restrictions to the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent (M.P.E.P. 608.01 (p)), and
 - b. access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. section 1.14 and 35 U.S.C. section 122; and
 - c. evidence of the accessibility of the culture(s) as set forth above is provided in the form of the attached copy of the contract with the above mentioned depository with respect to the deposited cultures.

| 23 September 2002 (Monday) | MILLENNIUM PHARMACEUTICALS, INC. |
|----------------------------|----------------------------------|
| | By K Ful So |
| | Kerri Pollard Schray |
| | Registration No. 47,066 |
| | 75 Sidney Street |
| | Cambridge, MA 02139 |
| | Telephone - 617-551-3676 |
| | Facsimile - 617-551-8820 |

Person authorized to sign on behalf of assignee





10801 University Blvd • Manasses, A 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

POD . BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Millennium Pharmaceuticals, Inc. Attn: Stephen Manning 75 Sidney Street Cambridge, MA 02139

Deposited on Behalf of:

Millennium Pharmaceuticals, Inc.

Identification Reference by Depositor:

Patent Deposit Designation

Plasmid: pfrhob165c3L Plasmid: pfrhob35911S

PTA-2084 PTA-2085

The deposits were accompanied by: __ a scientific description _a proposed taxonomic description indicated above. The deposits were received June 14, 2000 by this International Depository Authority and have been accepted.

We will inform you of requests for the strains for 30 years. AT YOUR REQUEST: X

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested June 28, 2000. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Barbara E. Coupé, Administrator, Patent Depository

Date: June 30, 2000

cc: Jean M. Silveri, Esq.



Budapest Treaty Deposits

American Type Culture Collection

10801 University Blvd., Manassas, VA 20110-2209 Phone (703) 365-2700; fax (703) 365-2745; e-mail applied-sci@atcc.org **ATCC**

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF THE BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

| A | L QUESTIONS MUST BE COMPLETED IN ENGLISH. PLEASE USE ONE FORM FOR EACH STRAIN DEPOSITED. Name of deposit. If microorganism, give complete scientific name including genus and species and source of material; If virus, give name, whether plant or animal, and source including geographic location; If cell line, give tissue and species, geographical source of isolation, and any known hazards associated (HIV, EBV, etc.); If genetic materials, give name of organism from which vector, clone or library is derived, source of the DNA insert identified by species (e.g. human, mouse) or scientific name, and give name of gene and identity of the host organism; If consortia or mixed culture, each component of the mixture must be identified; If seeds, embryos, insect eggs, etc., give common name, scientific name, and geographical source. | | | | | | |
|----------|---|--|--|--|--|--|--|
| | pfrhob165c3L | | | | | | |
| 2 | Strain designation (i.e., number, symbols, etc.) — pfchob/b5c3L The strain designation must correspond with the vial labels. | | | | | | |
| _ | | | | | | | |
| 3. | Is this an original deposit under the Budapest Treaty? YES | | | | | | |
| 4. | Is this a request for a conversion of a deposit already at ATCC to meet the requirements of the Budapest Treaty? If so please indicate ATCC designation. NO | | | | | | |
| 5. | Is this deposit a mixture of microorganisms or cells? NO | | | | | | |
| 6. | Provide details necessary to cultivate, test for viability, and store deposit. If mixture, provide description of components and a method to check presence. If plasmid, provide name of host and antibiotic resistance. | | | | | | |
| | pfrhoblose3L is a plasmed with resistance to Amp | | | | | | |
| 7. | Provide sufficient description so that ATCC may confirm deposit properties (e.g., Gram negative rod). ptrhob/6503L can be transformed, no E. Coli. and grown up, n Amp. | | | | | | |
| | a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list the antibiotics. | | | | | | |
| | b. If deposit is hybridoma, what is the isotype of antibody produced? | | | | | | |
| 8. | Is this strain hazardous to humans? NO Animals? NO Plants? NO Plants? NO If yes, what is the recommended biosafety level for working with this strain? (Refer to Biosafety in Microbiological and Biomedical Laboratories, 4th ed. U.S. Dept. of Health and Human Services at www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm]. | | | | | | |
| 9. | Availability: Prior to the Issuance of a U.S. Patent, ATCC will only make a culture available as instructed by the depositor or relevant patent office. Samples must be provided to a specific investigator if a pertinent patent office under the Budapest Treaty instructs ATCC to do so. The following questions must be answered: | | | | | | |
| | a) As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to anyone who requests a culture? If yes there are no restrictions on distribution. Answering no will ensure the deposit is not available until the patent has issued. Yes No _X | | | | | | |
| | b) As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to requestors which satisfy patent offices in countries not signatory to the Budapest Treaty? Yes No _X | | | | | | |
| | Please note that if you are converting your deposit to meet the requirements of the Budapest Treaty and your deposit has already | | | | | | |



been released for distribution due to the issuance of a U.S. patent, you cannot restrict it from further distribution.

| USPTO Rules and Regulations (37 CFR 1.80 | 98 [a][2]). | iture avaliable to an | yone who requests it, as allowed under |
|--|--|---|---|
| 10. ATCC will notify you of your ATCC number a Name of individual to notify: Jean M. Sil Fax: (617) 374-0074 | fter confirmation of via | ability testing is com | plete. |
| | | | |
| Payment by check, or credit card (Mastercard for billing have been made and approved. ATC | d, VISA or American E CC accepts Purchase | express), must acco Orders in the corre | mpany the deposit unless prior arrangements at amount: |
| Purchase Order No. P.O. # MA1350SO | | Check No. | |
| Credit Card number. Please indicate MasterC | ard, VISA, or AE | | |
| Exp. Date: | | | |
| | | (Please ty | pe or print clearly.) |
| Signature of card holder | | | |
| PAYMENT: ATCC MUST HAVE A BILLING ADDR | RESS CONTACT PER | RSON PHONE AND | A EAV NI MARER EOR ALL DEDOCITO. |
| | | | FAX NUMBER FOR ALL DEPOSITS: |
| | | | |
| | | | |
| Phone: | Fax: | | |
| 12. Name, address, telephone and facsimile num | nber of your attorney o | of record. Jean M | . Silveri. Esg. |
| Millennium Pharmaceuticals, I | nc., 75 Sidney | Street, Camb | ridge, MA 02139 |
| Tel: (617)679-7336, Fax: (617) |)374-0074 (Ref: D | locket or Case No. | ` |
| | | | |
| MUST BE COMPLETED. Deposited on beha company or institute and not an individual.) | Millennium Pha | management who o rmaceuticals, | wns the deposit. The owner is usually a |
| understand and agree that the deposit may not least 30 years after the date of deposit or 5 longer), and that if a culture should die or be corresponsibility to replace it with a living culture embryos, and seeds, it is my responsibility to stephen Manning Typed Name | o years after the date destroyed during the e of the same organi: supply a sufficient o | of the most recent life of the patent o sm or cell. In the co wantity for distribu | request for the deposit, whichever is in the period of time so specified, it is my ases of viruses, cell cultures, plasmids, tion for the period of time specified above |
| Address: 75 S. Arcy St. | Cambri | dae. MA | J2139 |
| Phone: 617-551-8851 Fax: | 617-551-89 | (D E-mail: _ | Manning @ mpi.com |
| ADDRESS SHIPMENTS AND FORM TO THE AT | TENTION OF: | Patent Depository American Type Cu 10801 University B Manassas, VA 20 | lvd. |
| STORAGE: Cultures are stored for 30 years from equired under the rules of patent offices in most FEES: For current fees, check our Web site at ww 703) 365-2700 ext. 320. All fees are subject to check the contract of the subject to check the subject the subject to check the subject the subje | water om regueet a | | |
| ATCC USE ONLY: ATCC DESIGNATION | RE | C'D | V.T. RESULT |
| lame of Deposit | | | |
| | | ooig/idiio/h, | Form BP/1 Rev. 2/00 |

Budapest Treaty Deposits

ATCC

American Type Culture Collection
10801 University Blvd., Manassas, VA 20110-2209
Phone (703) 365-2700; fax (703) 365-2745; e-mail applied-sci@atcc.org

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF THE BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

| A 1. | L QUESTIONS MUST BE COMPLETED IN ENGLISH. PLEASE USE ONE FORM FOR EACH STRAIN DEPOSITED. Name of deposit. If microorganism, give complete scientific name including genus and species and source of material; If virus, give name, whether plant or animal, and source including geographic location; If cell line, give tissue and species, geographical source of isolation, and any known hazards associated (HIV, EBV, etc.); If genetic materials, give name of organism from which vector, clone or library is derived, source of the DNA insert identified by species (e.g. human, mouse) or scientific name, and give name of gene and identity of the host organism; If consortia or mixed culture, each component of the mixture must be identified; If seeds, embryos, insect eggs, etc., give common name, scientific name, and geographical source. | | | | | | |
|-------------|---|--|--|--|--|--|--|
| | ptrhob3596115 | | | | | | |
| 2 | Strain designation (i.e., number, symbols, etc.) | | | | | | |
| | | | | | | | |
| 3. | Is this an original deposit under the Budapest Treaty? YES | | | | | | |
| 4. | Is this a request for a conversion of a deposit already at ATCC to meet the requirements of the Budapest Treaty? If so please indicate ATCC designation. NO | | | | | | |
| 5. | Is this deposit a mixture of microorganisms or cells? NO | | | | | | |
| 6. | Provide details necessary to cultivate, test for viability, and store deposit. If mixture, provide description of components and a method to check presence. If plasmid, provide name of host and antibiotic resistance. pfchob359bls is a plasmid with cost starce to Amp. | | | | | | |
| 7. | Provide sufficient description so that ATCC may confirm deposit properties (e.g., Gram negative rod). Pfc hol 359611 S can be temsformed in to E. ci. and gram up a Amp. | | | | | | |
| | a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? If so, please list the antibiotics. | | | | | | |
| | b. If deposit is hybridoma, what is the isotype of antibody produced? | | | | | | |
| В. | Is this strain hazardous to humans? NO Animals? NO Plants? NO Plants? NO If yes, what is the recommended biosafety level for working with this strain? (Refer to Biosafety in Microbiological and Biomedical Laboratories, 4th ed. U.S. Dept. of Health and Human Services at www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm]. | | | | | | |
| 9. | Availability: Prior to the issuance of a U.S. Patent, ATCC will only make a culture available as instructed by the depositor or relevant patent office. Samples must be provided to a specific investigator if a pertinent patent office under the Budapest Treaty instructs ATCC to do so. The following questions must be answered: | | | | | | |
| | a) As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to anyone who requests a culture? If yes there are no restrictions on distribution. Answering no will ensure the deposit is not available until the patent has issued. Yes No _X | | | | | | |
| | b) As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to requestors which satisfy patent offices in countries not signatory to the Budapest Treaty? Yes NoX | | | | | | |
| | Please note that if you are converting your deposit to meet the requirements of the Budapest Treaty and your deposit has already | | | | | | |

been released for distribution due to the issuance of a U.S. patent, you cannot restrict it from further distribution.

| USPTO Rules and Regulations (37 CFR 1.80 | 8 [a][2]). | s trie cuii | ore available | to anyone who req | uests it, as allowed under |
|---|--|---|---|---|--|
| 10. ATCC will notify you of your ATCC number at Name of individual to notify: Jean M. S11 Fax: (617) 374-0074 | fter confirmation | on of vial | bility testing is | complete. | |
| | | | | | nail: silveri@mpi.com |
| Payment by check, or credit card (Mastercard for billing have been made and approved. ATC | d, VISA or Ame CC accepts Pu | erican E ırchase | xpress), must Orders in the | accompany the decorrect amount: | posit unless prior arrangements |
| Purchase Order No. P.O. # MA1350S0 | | | Check No | | |
| Credit Card number. Please indicate MasterC | ard, VISA, or | AE | | | |
| Exp. Date: | Name sh | nown on | card: | | |
| | | | (Ple | ase type or print clea | ırly.) |
| Signature of card holder | *** | _ | | | |
| PAYMENT: ATCC MUST HAVE A BILLING ADDR | RESS, CONTA | CT PER | SON, PHONE | AND FAX NUMB | ER FOR ALL DEPOSITS: |
| | | | | | |
| | | | | | |
| | | | | | |
| Phone: | Fax: | | | | - |
| 12. Name, address, telephone and facsimile num | nber of your at | tomey o | f record. <u>Je</u> | an M. Silver | i, Esq., |
| Millennium Pharmaceuticals, I | nc., 75 S | idney | Street, | <u>Cambridge, M</u> | A 02139 |
| Tel: (617)679-7336, Fax: (617 | <u>)374-0074</u> | (Ref: D | ocket or Case | No |) |
| company or institute and not an individual.) | Millenniu | m Phai | rmaceutic | als, Inc. | |
| I understand and agree that the deposit may r (at least 30 years after the date of deposit or 5 longer), and that if a culture should die or be o responsibility to replace it with a living culture embryos, and seeds, it is my responsibility to | i years after to destroyed du e of the same supply a suff | he date ring the organis ilcient q | of the most r life of the pa sm or cell. In uantity for di | ecent request for tent or the period the cases of virus stribution for the | the deposit, whichever is of time so specified, it is my ses, cell cultures, plasmids, period of time specified above |
| Stephen Manina | The state of the s | inhe | Mari | _ | 6/13/00 |
| Typed Name | | Signatu | re | \supset | Date |
| Stephen Manning Typed Name Address: 75 Sidney St. | Cambr.d | 5 | MA . | <u>32139</u> | |
| Phone: <u>617-551-86 31</u> Fax | : <u>617-551</u> | 1-89(0 |) E-m | ail: Man.' | @ Mpi. com |
| ADDRESS SHIPMENTS AND FORM TO THE AT | TENTION OF | : | 10801 Unive | oe Culture Collecti | |
| STORAGE: Cultures are stored for 30 years from required under the rules of patent offices in most FEES: For current fees, check our Web site at w. (703) 365-2700 ext. 320. All fees are subject to c | countries. ww.atcc.org. re | | | | |
| ATCC USE ONLY: ATCC DESIGNATION | | RE | C'D | V.T. | RESULT |
| Name of Deposit | | | | | |
| - | | | 20.911 | | Form BP/1 Rev. 2/00 |